

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
OFFICE OF ALTERNATIVE MEDICINE

ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL  
SUMMARY MINUTES OF MEETING

September 16-17, 1996

Bethesda, Maryland

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
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The Alternative Medicine Program Advisory Council (AMPAC) of the Office of Alternative Medicine (OAM) convened for its seventh meeting at 8:39 a.m.\* on September 16-17, 1996 in the Versailles II Room of the Holiday Inn at 8120 Wisconsin Avenue in Bethesda, Maryland. Dr. James S. Gordon presided as Chair. The meeting was open to the public.

\*All times are approximate.

**AMPAC MEMBERS PRESENT**

The Honorable Berkely Bedell  
Dr. Brian M. Berman  
Ms. Carola Burroughs  
Dr. Barrie Cassileth  
Dr. David M. Eisenberg  
Dr. Noreen Cavan Frisch  
Dr. James S. Gordon  
Mrs. M. Linden Griffith  
Mr. Gar Hildenbrand  
Sister Charlotte Kerr  
Dr. Ralph Moss  
Dr. Lorenz Keng-Yong Ng  
Dr. Richard S. Panush  
Dr. Beverly Rubik  
Ms. Ellen Silverstone

**AMPAC MEMBERS ABSENT**

Mrs. Carolene Marks

**OAM STAFF PRESENT**

Dr. Cheong C. Chah, Program Officer (NINR)  
Dr. Li-Chuan Chen, IRTA Fellow  
Dr. Geoffrey P. Cheung, Executive Secretary, AMPAC  
Ms. S. Elizabeth Clay, Committee Management Officer, AMPAC  
Ms. Anita Greene, Program Officer  
CAPT Nancy Hazleton, Program Officer  
Dr. Carole Hudgings, Program Officer

Dr. Wayne B. Jonas, Director (Ex Officio)  
Dr. Richard L. Nahin, Program Officer  
Ms. Ann Scheppach, Senior Advisor for Legislation and Strategic Planning

#### **STAFF OF OTHER NIH COMPONENTS PRESENT**

Dr. John Ferguson, OMAR  
Dr. Stephen Groft, ORD  
Dr. Margery Grubb, CMO/OD  
Dr. William Harlan, ODP/OD  
Dr. William Kammerer, ICD/CC  
Dr. Ruth L. Kirschstein, Deputy Director, NIH  
Ms. Angela Magliozzi, NIAID  
Janice Ramsden, OD  
Pamela Shannon  
Dr. Alan I. Trachtenberg, NIDA  
Dr. Sue Van Lenten, NICHD

#### **OTHERS PRESENT**

Mr. Mac Beckner  
Ms. Lisa Burns, Audio Reporting Service  
Mrs. Kelley Long Gillespie, Courtesy Associates  
Mr. Daniel W. Hawkins, Audio Reporting Service  
Ms. Melanie Kobrin  
Ms. Amy Landsbaum, Courtesy Associates

#### **MEMBERS OF THE PUBLIC PRESENT**

J.P. Borneman, Esq., APCS, Bryn Mawr, PA)  
Mr. Dannion H. Brinkley (Aiken, SC)  
Dr. Barbara Brewitt, Chief Scientist, Bastyr University AIDS Research Center (Seattle, WA)  
Dr. Daniel Eskinazi, Hinda and Richard Rosenthal Center for Alternative and Complementary Medicine, Columbia University (New York, NY)  
Ms. Pamela Farmer, Acupuncturist (Takoma Park, MD)  
Tracy A. Fox, Government Relations Team, American Dietetic Association (Washington, DC)  
Jerry A. Green, Esq., Medical Decisionmaking Institute (Mill Valley, CA)  
Reg Griffin, Marketing Director, ESA Labs (Chelmsford, MA)  
Dr. Lowell T. Harmison (Washington, DC)  
Mrs. Christeene Hildenbrand, Vice-President and Director, Gerson Research Organization (San Diego, CA)  
Dr. Freddie Ann Hoffman, Deputy Director, Medicine Staff Office of Health Affairs, FDA  
Dr. Hope Kellman, Research Director, Health Technologies (Silver Spring, MD)  
Ms. Nancy D. Kolenda, Coordinator, Center for Frontier Sciences,

Temple University (Philadelphia, PA)  
 Dr. Fredi Kronenberg, Principal Investigator, Center for CAM  
 Research in Women's Health, College of Physicians and Surgeons,  
 Columbia University (New York, NY)  
 Dr. J. William LaValley (Austin, TX and Chester, Nova Scotia,  
 Canada)  
 Dr. Floyd E. Leaders, Jr., President, The Leaders Group, Inc.  
 (Rockville, MD)  
 Ms. Barbara Mayerman (Arnold, MD)  
 Ms. Sandra McLanahan (Buckingham, VA)  
 Dr. Paul Melbacy, ESA Labs (Chelmsford, MA)  
 Ms. Rebecca Miller, Nurse Practitioner, Department of State  
 (Washington, DC)  
 Ms. Martha Oelman, Media Liaison, National Center for Homeopathy  
 (Bellbrook, OH)  
 Mr. John Parker, Editor, *The Blue Sheet* (Chevy Chase, MD)  
 Dr. Georgia J. Persinos, Editor, *Washington Insight* (North  
 Bethesda, MD)  
 Sally Rosen, Temple University (Philadelphia, PA)  
 Mr. Gary Sandman (Laytonsville, MD)  
 Dr. N. Schoenberger, Kessler Institute for Rehabilitation-  
 University of Medicine and Dentistry Center for Research in  
 Alternative and Complementary Medicine in Stroke and Related  
 Neurological Disorders (West Orange and Newark, NJ)  
 Mr. Maury Silverman, (Silver Spring, MD)  
 Dr. Robert F. Spiegel, Director, Psycho-Medical Chirologists  
 (Silver Spring, MD)  
 Dr. Leanna J. Standish, Research Director, Bastyr University AIDS  
 Research Center (Seattle, WA)  
 Dr. Lea Steele Levin (Virginia Beach, VA)  
 Mr. Jack Thomas, Publisher, *Touch Therapy Times*, Maryland  
 Ms. Jackie Wootton, Director, Information Resources, Hinda and  
 Richard Rosenthal Center for Alternative and Complementary  
 Medicine, Columbia University (New York, NY)] (North Potomac, MD)  
 Ms. Eua Joe Wu, Rolfer, Roling Associates (Roanoke, VA)

**I. CALL TO ORDER AND OPENING REMARKS**

**Dr. Geoffrey P. Cheung, Executive Secretary, AMPAC and Dr. Wayne B. Jonas, Director, OAM**

Dr. Cheung opened the seventh meeting of the AMPAC. Dr.  
 Jonas welcomed attendees and extended a special greeting to  
 Dr. William Harlan, Associate Director, Office of Disease  
 Prevention/Office of the Director (ODP/OD). Dr. Cheung  
 recognized the following NIH staff: Dr. John Ferguson,  
 OMAR; Dr. Marjorie Grubb, CMO/OD; Ms. Angela Maggliozi,  
 NIAID; Ms. Janice Ramsden, OD; Dr. Alan I. Trachtenberg,  
 NIDA; and Dr. Sue Van Lenten, NICHD.

Dr. James Gordon stated that Dr. Jennifer Jacobs resigned  
 from Council for personal reasons, and Mrs. Carolene Marks

was unable to attend because a family member was seriously ill. Nominations for new AMPAC members have been forwarded to the Secretary, DHHS. Dr. Cheung indicated that the terms of AMPAC members who were about to rotate off the Council will be extended through the February 10-11, 1997 AMPAC meeting.

**II. REMARKS OF THE ASSOCIATE DIRECTOR, ODP/OD**  
**Dr. William Harlan, Associate Director, ODP/OD**

The OAM was transferred from the Office of Science Policy (OSP) to the ODP due to a restructuring of the OD that was approved on August 1, 1996. Dr. Jonas will continue to attend weekly OD Senior Staff meetings and will have as much, if not more, access to the Director of the NIH.

The OAM will be overseen by Dr. Harlan, who has similar responsibilities for other ODP components including the Office of Dietary Supplements (ODS); the Office of Rare Disease Research (ORDR); and the Office of Medical Applications of Research (OMAR), which will host an acupuncture consensus conference in 1997. He also directs the Women's Health Initiative prevention trial. Dr. Harlan brings to the OAM extensive experience with large definitive clinical trials, and will emphasize the creation of synergism between the OAM and other OD offices.

A discussion followed Dr. Harlan's remarks. Dr. Harlan observed that RCTs may not always be feasible in CAM. Different approaches and designs may need to be considered.

Because larger RCTs are very costly, the OAM will have to form partnerships with appropriate ICDs.

Dr. Barrie Cassileth and Dr. Gordon moved that "the Office give [the AMPAC] important information about structural...and programmatic changes as soon as possible".  
The motion was passed unanimously.

**III. PRESENTATION AND DISCUSSION: OAM DIRECTOR'S REPORT**  
**Dr. Wayne B. Jonas, Director, OAM**

Dr. Jonas highlighted selected products, services, and activities of the OAM functional sections. (The AMPAC received briefing books containing summary functional section reports.)

**PUBLIC INFORMATION AND MEDIA RELATIONS**

Priorities include the development of information packets and formalization of the packet review and approval process.

A contract for management of the public information service

will be awarded before the end of September. The contractor will be responsible for developing packets on a series of topics including cancer.

As part of the effort to create a fair procedure for packet development and review, the OAM met with communication and conflict management experts to consider issues associated with the closure of the Burzynski antineoplaston trial, and to examine approaches for developing and managing medical literature in Europe and elsewhere.

The OAM process will include three levels. At level 1, packets will be reviewed by at least three groups comprised of experts in CAM, methodologies, and clinical conditions. At levels 2 and 3, reviews will be performed by the OAM and other ICD clearinghouses. Feedback will be obtained from the latter on aspects such as format, readability, and relationship to other NIH public information. OAM packets should complement materials presented by other ICD clearinghouses. A standard clearance procedure that addresses distribution, cost, and justification issues also must be completed.

Media relations and maintaining accurate, appropriate communication regarding the OAM also are priorities. A demo page that currently is undergoing a second OAM review will provide not only a Web site but also a way of systematically accessing information on all OAM activities.

#### **DATABASE AND EVALUATION**

An operating procedure for conducting systematic reviews has been established, one review has been completed, and several are in progress. Dr. Carole Hudgings is working with the CAM Research Centers to develop mechanisms for the electronic exchange of research data. Dr. Jonas will travel to Germany and China to explore approaches used by various database groups.

Continued development of the OAM Research Database and the OAM Internal CAM Research Library is a high priority. A subset of literature on breast neoplasms comprising approximately 300 articles was chosen to test a study-design-based classification system created by Drs. Jonas and Hudgings. The articles are being analyzed to extract data on parameters such as study design, intervention, CAM modality, and outcomes.

A prominent mainstream publishing company has agreed to publish papers from the April 1995 OAM methodologies conference. Dr. Jonas will select the papers.

Dialog with the NLM has occurred concerning the CAMLINE. The OAM must develop its internal database and evaluation mechanisms before this initiative can proceed. The OAM is working with the NLM to make CAM information already in the NLM more accessible. A separate database support contract will be awarded before the end of September.

## **EXTRAMURAL AFFAIRS**

On September 9-10, the OAM met with the Principal Investigators of the 10 Centers co-funded by the OAM and various ICDs. Deliverables requested by the OAM range from Research Opportunity Disposition Summary (RODS) sheets to draft proposals for larger trials that will be submitted to ICDs). Following are highlights of selected Center activities.

UC-Davis (asthma and immunology) has funded two grants examining the effects of orally administered wheatgrass juice on allergic rhinitis and asthma, and the role of self-administered acupressure versus sham treatment on pulmonary function and quality of life among asthmatics. Other efforts include development of eight new research proposals, a technical assistance and education program, and a practitioner survey.

The University of Virginia (pain) has prepared a Standardized Individual Differences Profile and detailed technical assistance instructions on research project development. Two projects are evaluating the effectiveness of chiropractic for TMJ and the diagnostic accuracy of subtle energy devices. Funding will be sought to assess the efficacy of post-operative massage for female laparotomy patients, and to test the effects of binaural beat stimulation on EEG.

By the end of 1996, the Kessler Institute for Rehabilitation/University of Medicine and Dentistry-New Jersey (neurological disorders and stroke) will have pilot research underway on nine CAM treatments for stroke, spinal chord injury, and traumatic brain injury.

Columbia University (women's health) is performing qualitative research on ethnobotanical therapies for fibroids, endometriosis, hot flashes, and menorrhagia. Funding is being sought to examine traditional Chinese medicine for uterine fibroids; mind/body interventions and herbal medicines for hot flashes; and Tibetan medicine for metastatic breast cancer. Proposals also include a national survey of CAM use among women.

The University of Texas (cancer) is preparing state-of-the-science reviews, networking with practices in the United States and abroad, and establishing a prospective outcomes monitoring system. Protocols are under development to evaluate Korean ginseng for chemopreventive activity in vitro, Flavone dilution cytotoxicity, and Melatonin with Tamoxifen for metastatic breast cancer.

Harvard Medical School (general medicine) is developing protocols for RCTs comparing CAM with conventional medicine (CM) for acute low back pain, and comparing acupuncture and therapeutic massage with each other and with the use of self-care education materials for chronic low back pain. Other projects include a meta-analysis of placebo response rates in hypertension patients, the updating of a national CAM use survey, local surveys for specific conditions, research on liability and practice issues, and CAM education programs.

Hennepin County Medical Center (addiction) has provided technical assistance to more than 123 groups and funded two research Fellows. Projects are being developed or implemented on homeopathy for drug abuse, culturally specific models of chemical dependency treatment for Native Americans, a craving measurement device, symptom-based acupuncture and Kudzu for alcoholism, and animal studies of Radix Puerariae and electro-acupuncture for drug abuse.

Bastyr University (HIV/AIDS) is surveying CAM practitioners and will prospectively monitor 2,000 patients. Two grants have been funded on serial agitated dilutions (SADs) of insulin-like growth factors (IGFs) and Pet Morrow (a traditional Chinese medicine formula) with UCSF; a systematic review of anti-HIV natural products is in progress; and other projects are examining Phase I Tyrosine Kinase inhibition, SAD biologics screens, and acupuncture versus moxibustion.

The University of Maryland (pain) has established the CAMPAIN research database, and undertaken systematic reviews in acupuncture and hypnotherapy. Two studies on acupuncture for osteoarthritis in the elderly and post-operative oral pain have been completed as well as a national survey of primary care practitioners. A larger trial is being developed to confirm the osteoarthritis study findings. An official Complementary Medicine Field has been established within the Cochrane Collaboration due largely to the efforts of this Center and the OAM.

Stanford University (frailty in the elderly) has begun a



series of seminars for the Stanford community, and has received a donation of 10,000 articles on exceptional events. Proposals and projects are being developed on CAM utilization and insurance coverage and CAM therapies for congestive heart failure, post-menopausal problems, osteoarthritis, and neurological and musculoskeletal disorders.

## **RESEARCH DEVELOPMENT AND INVESTIGATION**

The elements of a research prioritization and management process are in place or under development. Prioritization entails application of (1) principles used by the OAM and the Centers that were outlined in the June 1996 AMPAC meeting briefing book), and (2) guidelines developed by the Institute of Medicine (IOM) that basically apply to all medical research.

The OAM has established operating procedures for research agenda and methods development, which the Centers and other groups are invited to use. The OAM probably will cooperate with the OAR in identifying research methods for specific projects.

Procedures for practice assessment reporting have been formalized. Reports in two formats were completed on seven practice assessments conducted since the June 1996 AMPAC meeting. Prospective outcomes monitoring was found to be appropriate for at least one-half of the practices. The practices were blinded because they had not yet approved the reports, a number of practices did not wish to be identified at this stage of development, and no research had occurred in other instances.

Dr. Li-Chuan Chen is continuing the assessment of evidence for anticancer activity in phenylacetate, phenylacetylglutamine, and other antineoplastons. His investigation includes, but is not limited to, compounds examined by Dr. Burzynski. Dr. Cheung noted that the OAM's interest in the entire family of compounds should not be confused with the present status of patient accrual by Dr. Burzynski or any other investigator.

The OAM is working with the DRG to tag CAM-related applications, which will facilitate identification of applications in high-priority OAM areas and collaboration with ICDs. A list of 454 consultants has been assembled and evaluated from which the DRG can draw to conduct peer reviews. The process for locating appropriate peer

reviewers in CAM areas is not yet fully developed.

#### **INTERNATIONAL AND PROFESSIONAL LIAISON**

By the end of September, the OAM anticipates receiving notification of acceptance as a World Health Organization (WHO) Collaborating Center in Traditional Medicine. The OAM will help to enhance communication among the WHO Centers and will assist in coordinating Center activities. For 1998, the OAM is planning a conference to formulate an international research agenda in traditional, complementary, and alternative medicine.

The AMA and other CM groups are increasingly recognizing the need for physician education in CAM. A full professor will spend his sabbatical working with the OAM on professional education initiatives.

The preliminary recommendations developed at the National Conference on Medical and Nursing Education in Complementary Medicine (June 5-7) were revised in accordance with comments made by participants and the public, and were forwarded to the Blue Ribbon Panelists for review. Major medical education groups around the country also will provide input.

In addition, Dr. Gordon suggested that the recommendations be sent to Council members and conference attendees. Efforts will be made to publish the recommendations in a journal highly visible to the conventional academic community. The recommendations also will be posted on the OAM home page.

#### **INTRAMURAL RESEARCH TRAINING PROGRAM**

The OD has approved a three-year OAM Intramural Research Training Program (IRTP). A search is underway for a Research Training Director. Potential lab space has been identified. It is hoped that Fellows will be selected by July 1998. Work already has begun to develop intramural projects with other ICDs. For example, the OAM and the NIAAA will use Pet scanning to investigate the effects of acupuncture on brain serotonin levels in alcoholics. The OAM and the NIAAA have advertised for a clinical Fellow. They will collaborate on Fellow selection and training as well as project development. The NIAAA will supply the PET scanner.

#### **LEGISLATION AND PLANNING**

Priorities are congressional relations and oversight of strategic planning activities.

## **ADMINISTRATIVE OPERATIONS**

All activities in this functional section are priorities including human resource management, budget management, procurement, space management, administrative services, and contract management.

### **IV. REMARKS OF THE DEPUTY DIRECTOR, NIH Dr. Ruth L. Kirschstein, Deputy Director, NIH**

Despite last year's budgetary difficulties, the OAM has grown and flourished under the leadership of Drs. Jonas and Cheung. The House allocated approximately \$7.8M to the OAM when it passed the NIH fiscal year 1997 budget. The Senate Appropriations Subcommittee and Full Committee passed the budget one week ago. The budget plan for the OAM is \$8M. If a bill reaches the floor, the Senate appropriation will be \$8M, the House appropriation will be roughly \$7.6M, and a compromise will be made. If there is no bill on the floor, a continuing resolution, possibly at the fiscal year 1996 funding level, could last as long as six months.

*The New York Times* printed the correction of an inaccurate statement attributed to Dr. Kirschstein that some grant applications were not peer reviewed.

A discussion followed Dr. Kirschstein's remarks. Topics included the OAM's ability to bring radically new ideas into the NIH and carry them to fruition, wellness, the AMPAC's role, and the importance of preventing conflicts of interest. Dr. Kirschstein observed that wellness is a focus of the OAM. She expressed the hope that the AMPAC, as part of the NIH community, will advise the OAM based on members' CAM experience and knowledge. Dr. Gordon conveyed Council's appreciation for Dr. Kirschstein's support of the OAM.

### **V. PRESENTATION: Shifting Paradigms in Growth Factor/Cytokine Biotechnology: The Science, the Paradigm, and the Interface Dr. Barbara Brewitt, Chief Scientist, Biomed Comm Inc. and Dr. Leanna Standish, Research Director, Bastyr University HIV/AIDS Research Center (Seattle, WA)**

A Phase I double-blind, placebo-controlled study funded by the OAM was conducted to determine if oral delivery of four homeopathically prepared IGFs and a combination would raise lymphocytes in HIV-positive patients who were not receiving conventional antiviral or steroidal therapy. After four months, the placebo group was crossed over to treatment. An open-label study was conducted for another nine months.

Patients in the treatment group gained weight , those in the

placebo group lost weight, and the difference in weights was highly statistically significant. Patients in the placebo group started to gain weight when they were crossed over. The treatment group experienced no opportunistic infections for one year, while 20 percent of the placebo group developed infections within three months. Measured viral load in the long-term treatment group showed a continual downward trend. Platelet count increased in patients with low counts and did not change in patients with normal counts. There was an upward trend in serum calcium and phosphorus levels for the treatment group, and a downward trend for the placebo group.

Statistically significant decreases in depression over a three-month period were obtained in a preliminary assessment of a single homeopathically prepared IGF administered to healthy persons diagnosed as depressed and on the verge of taking conventional antidepressants.

Dr. Standish outlined pressing research questions and needs associated with high-dilution biologics and pharmacologics for the treatment of HIV/AIDS and cancer. She expressed the hope that streamlined regulatory IND or homeopathic pharmacopeic procedures and a set of policies will be developed quickly to expedite research in this area.

## **VI. DISCUSSION: OAM PRIORITIES AND STRATEGIC ISSUES**

The following topics were addressed: Cancer information test packets and quality assurance for public information, methodology and contract for prospective outcomes monitoring of cancer therapies, IOM prioritization process, other potential OAM research projects, *Evidence-Based CAM Journal*, international and professional liaison activities, FDA liaison for IND development, renaming of the OAM, and projected OAM budget allocations.

### **CANCER INFORMATION TEST PACKETS AND QUALITY ASSURANCE FOR PUBLIC INFORMATION**

Dr. Jonas suggested that the OAM undertake a one-year pilot project in cooperation with the NCI to develop test packets on cancer therapies, drawing on information compiled by the Cancer Information Service at the University of Texas and with AMPAC involvement including the Public Information Working Group. This pilot project will assist the OAM in creating a prototype development and review process for public information.

Dr. David Eisenberg noted that Council has continuously focused on the need for public information to be

thoughtfully evaluated, fair, and nonjudgemental. Multiple outside reviews should be obtained, Mr. Gar Hildenbrand stated, and CAM developers should be involved. Dr. Ralph Moss indicated that review guidelines should require consultation with CAM proponents and consumers whenever possible. A group that is not invested in the choices made by patients should be included in the review process.

Dr. Eisenberg suggested that the CAM Centers be asked to compile lists of oncologists with whom they collaborate who can participate in prospective outcomes monitoring, and assist the OAM in working with the NCI to assess information.

The Honorable Berkely Bedell asked that the minutes reflect the AMPAC's support for Dr. Jonas on this cooperative project and as well as some members' concern; and noted the Council's hope that Dr. Jonas will work with the Public Information Working Group.

Dr. Moss requested that the AMPAC receive fax communiques of major news stories about the OAM. Ms. Anita Greene observed that distributing CAM news clips to Council is a specific task under the new Clearinghouse contract, and asked Council to send her relevant news stories as well.

#### **METHODOLOGY AND CONTRACT FOR PROSPECTIVE OUTCOMES MONITORING OF CANCER THERAPIES**

Dr. Jonas solicited guidance on temporarily shifting the emphasis from conducting new practice assessments to developing a methodology for a prospective outcomes monitoring system. While establishing the system, OAM staff will perform fewer practice assessments. When the mechanism is in place, the OAM will have the capability to double or triple the number of assessments.

Noting the OAM's mandate to conduct field investigations as well as the importance of the prospective outcomes monitoring system, Mr. Bedell recommended that the OAM not decrease the number of assessments. The OAM needs to collect more information on the most promising CAM practices before conducting in-depth evaluations of treatments. Consideration should be given to simultaneously developing the prospective outcomes monitoring system and continuing the assessments.

Dr. Cheung observed that the 10 CAM Centers each have submitted 10 RODS, and some have provided more. The investigators are not OAM staff, but they are funded through the OAM's Extramural Program and conduct the assessments

using an OAM-developed instrument.

Dr. Cassileth moved "that we understand the synergy between [continuing the] practice assessments and the development of methodology to improve those practice assessments in the future, and that we continue both of those activities in [the] way that [Dr. Jonas deems] most appropriate". The motion was passed with 12 in favor and 1 opposed.

Early in 1997, the OAM hopes to convene a group of experts including AMPAC members, CAM practitioners, oncologists, oncology researchers, and epidemiologists who will assist the OAM in refining a methodology for the prospective outcomes monitoring of cancer therapies. An independent research organization will be contracted to operate the prospective outcomes monitoring system.

#### **IOM PRIORITIZATION PROCESS**

As outlined during the June 1996 AMPAC meeting, the IOM has been asked to develop a research prioritization process incorporating important CAM principles and assumptions. Using a format somewhat similar to a consensus conference, an independent panel will formulate the prioritization process through a series of meetings during which panelists will hear presentations from experts including CAM practitioners, researchers, and methodologists. The IOM will not prepare a CAM research agenda. By December 1996, the OAM will query AMPAC members for feedback concerning (1) topical areas, (2) key papers summarizing important CAM issues, and (3) suggestions for panelists and presenters.

Dr. Cassileth moved "that we proceed with the IOM [activity] at a maximum of \$500,000 [per] year." The motion was passed unanimously.

#### **OTHER POTENTIAL OAM RESEARCH PROJECTS**

In lists of priorities prepared by AMPAC members during the June 1996 meeting and tabulated after adjournment, Council indicated that funds should be allocated to more definitive research if the 1997 budget is larger than anticipated. In addition to the prospective outcomes monitoring system for cancer therapies and the IOM prioritization process, Dr. Jonas solicited recommendations concerning six potential OAM research projects: (1) An RCT on EDTA chelation for cardiovascular disease, (2) an RCT on integrated CAM/CM treatments for cancer versus CM alone, (3) an RCT on hypericum for mild-to-moderate depression, (4) an RCT on comparative approaches for osteoarthritis, (5) a laboratory evaluation of direct mental influence, and (6) an in-

vivo/in-vitro evaluation of high-dilution homeopathic immunotherapy.

The contract for the cancer therapies prospective monitoring system, the IOM prioritization process, and the laboratory evaluation of direct mental influence are largely within the scope of the OAM's current budget. The RCTs can be accomplished only through collaborative relationships. The evaluation of homeopathic immunotherapy can be developed through the I RTP.

Ms. Ellen Silverstone stressed that cancer is an area of critical need; 78 percent of inquiries received by the OAM Clearinghouse are cancer related according to data provided at a previous AMPAC meeting. Dr. Ralph Moss recommended narrowing the focus of the cancer RCT to address concurrent use of antioxidants and chemotherapy. Collaboration with the NCI and UC-Irvine should be considered. Dr. Eisenberg indicated that the Stanford CAM Center would gladly work with the Harvard CAM Center on an EDTA RCT, and that a well-designed experiment might interest the NHLBI as well. Mr. Hildenbrand proposed introducing a third arm and building a head-to-head comparative outcomes study into the RCT.

Dr. Beverly Rubik recommended developing an RFA for basic research on a number of subtle energies or energy medicine mechanisms rather than limiting the research focus to homeopathic histamine.

Dr. Richard Panush proposed four selection criteria for research projects: (1) The project should address a health problem that is important and common, (2) the CAM treatment under investigation should be unconventional but not so highly charged that this feature becomes an obstacle to study interpretation and acceptance, (3) the project should be feasible within a reasonable time frame, and (4) the project should be undertaken in collaboration with initiatives already underway or with credible investigators.

This cooperative approach will facilitate widespread acceptance of study results, and could provide opportunities to obtain additional funding from industry and other sources outside the NIH.

Sister Charlotte added that projects should be politically relevant. Mr. Hildenbrand emphasized the importance of adequately addressing social influence issues up front.

Dr. Panush cited depression and musculoskeletal disease as examples of health problems that meet the proposed selection criteria. While clearly important, the RCTs on cancer and cardiovascular disease should not be undertaken

first because they would be expensive and outcomes would be complicated to address.

Dr. Cassileth moved "that we encourage the [OAM] to look into the feasibility with [the] NCI, etc. of piggybacking onto ongoing randomized clinical trials in cancer various complementary and alternative therapies." The motion was passed unanimously.

Dr. Jonas indicated that the OAM will begin the developmental process for many of the proposed RCTs including exploration of opportunities to add onto existing research.

Poverty, racism, violence, and divorce are some of the major problems that should be considered in light of the commitment to preventing disease and promoting wellness, Sister Charlotte remarked. Dr. Gordon asked that the topic of understanding connections between issues associated with research on specific modalities and illnesses, and larger socioeconomic and psychological issues, be added to the agenda for the next AMPAC meeting. Discussion could include establishment of a Center on wellness.

#### **EVIDENCE-BASED CAM JOURNAL**

As a model for the *Evidence-Based CAM Journal*, Dr. Jonas proposed the *Annals of Evidence-Based Medicine*. Dr. Panush suggested that the OAM contact Dr. Frank Davidov and offer to contribute a CAM section for the journal/2)31. Dr. Eisenberg recommended that information on the *Annal's* requirements for formatting research projects be made available to the Centers so that they can design their studies accordingly.

#### **INTERNATIONAL AND PROFESSIONAL LIAISON ACTIVITIES**

Greater focus is needed on European and Western CAM, Ms. Carola Burroughs observed, and homeopathy is sufficiently important to be designated as an initiative given its use worldwide. Dr. Gordon suggested that more time be devoted to issues involving professional organizations, and that the International and Professional Liaison Working Group meet by teleconference in the near future.

Mr. Hildenbrand asked that the subject of birthing and midwifery be noted as missing from International and Professional Liaison activities. This area is one of many in indigenous medicine that need to be supported rather than replaced by high tech medicine, CAPT Nancy Hazleton indicated. Sister Charlotte commented on the link between



the Beijing conference, struggles faced by women around the world, and the fact that women are identified as the carriers of health care and healing.

If additional funds become available, Dr. Eisenberg suggested that consideration be given to providing extramural training in CAM for physicians and nurses who are completing their primary care or subspecialty training. This experience would prepare clinicians to interact responsibly with the CAM community, but not to deliver alternative care. CAM experts would serve as faculty. Dr. Eisenberg asked that this topic be added to the agenda for the next AMPAC meeting.

#### **FDA LIAISON FOR IND DEVELOPMENT**

Dr. Jonas noted that collaboration with the FDA is occurring on two levels: (1) Requests for IND-related guidance on specific research projects and (2) liaison with the FDA through committee work and the detailing of FDA staff to the OAM. In addition, an AMPAC FDA Liaison Working Group could be established to advise the OAM on IND and other issues that influence the OAM's ability to advance CAM research.

In accordance with a motion passed at the June 1996 AMPAC meeting, an informal working group will be created to write a letter for presentation to the OAM regarding some AMPAC members' concern that activities undertaken by a portion of the FDA negatively affect CAM research. Divergent views were expressed concerning this communication. The letter and the official record should state clearly that not all Council members supported its preparation, Dr. Panush indicated.

The point was made that FDA regulatory and enforcement activities are outside the scope of the OAM. However, the OAM is engaged in various FDA liaison activities. The OAM assists its grantees in understanding the IND application process. A series of meetings on the topic of INDs has been held with the FDA. Dr. Robert Temple (FDA) has been invited to serve as a nonvoting, ex officio AMPAC member. Meetings are continuing with the FDA to promote greater understanding of unique issues faced by the OAM and CAM investigators such as Dr. Brewitt. Drs. Jonas and Cheung meet regularly with Dr. Freddie Ann Hoffman (FDA) and Drs. Fredi Kronenberg and Judith Stern, Principal Investigators of the Columbia University and UC-Davis CAM Centers. Over the next nine months, the OAM and the FDA will explore FDA regulatory mechanisms that could be useful for CAM research. Drs. Hoffman and Cheung have discussed reinstating the OAM-FDA Working Group formed when Dr. Joseph Jacobs was Director of

the OAM.

Dr. Rubik asked that the AMPAC be informed of legislation involving INDs. Briefings could be provided at Council meetings. The AMPAC and possibly the OAM need to take a more proactive role in discussing the extraordinary IND-related difficulties faced by CAM investigators. Dr. Gordon recommended that the AMPAC FDA Liaison Working Group begin assisting the OAM, and that Ms. Ann Scheppach prepare a summary of administrative and legislative developments for Council before the next AMPAC meeting.

#### **RENAMING OF THE OAM**

Dr. Cassileth moved "that we officially change the name of the [Office of Alternative Medicine (OAM)] to [the Office of Complementary and Alternative Medicine (OCAM)]." The motion was passed unanimously.

#### **PROJECTED OAM BUDGET ALLOCATIONS**

AMPAC members reviewed and approved the proposed fiscal year 1997 budget with one modification

#### **VII. CONSIDERATION OF MINUTES**

Drs. Cheung and Gordon signed off on the minutes of the June 1996 AMPAC meeting. Dr. Cheung requested that AMPAC members submit any corrections to him in writing for inclusion in the minutes of the next Council meeting as an amendment to the record.

#### **VIII. PUBLIC COMMENTS**

Dannion H. Brinkley, Author and Hospice Volunteer, praised *Alternative Medicine: Expanding Medical Horizons--A Report to the NIH on Alternative Medical Systems and Practices in the United States* (December 1994), which he has used extensively in hospice work with powerful results. CAM practices also played a central role in Mr. Brinkley's recovery from severe injuries.

Dr. Barbara Brewitt, Chief Scientist, Biomedcomm, Inc., outlined difficulties related to the IGF study for HIV patients. A delay in announcing the grant awards shortened the grant period by three months. The grant money could be lost if the grant is not approved within two weeks. The RFA did not state that an IND may be required. Even for a scientist experienced with Proposal writer who had written many grant proposals, preparing the IND was an overwhelming

process. The NDA is another huge task. Many companies assign four or five people fulltime for several months to one IND, and organizations have regulatory divisions that prepare NDAs. An investigator can experience success with IND and accomplish nothing with the NDA. Thus, published therapies whose effectiveness has been demonstrated scientifically cannot reach patients in need.

A large amount of intellectual property was jeopardized because of the information that had to be shared with pharmaceutical companies during the difficult relationship building process, although the great strides made in this area would have been impossible without the OAM grant. Legal counsel has been very expensive. Dr. Brewitt expressed regret that this HIV study became a test case, noting that she has had to respond for nine months to calls from dying patients asking when they can join the study.

Mr. Hildenbrand emphasized the importance of enabling Dr. Brewitt to provide input into the AMPAC FDA Liaison Working Group.

Jerry Greene, Esq., Medical Decisionmaking Institute, commented on the significant conceptual and professional implications of creating research projects that apply holistic modalities to the treatment of pathology. The OAM should ask project initiators to clarify whether they intend to research the treatment of a pathology or the treatment of a person with a pathology. A fruitful question to explore is the nature of the relationship between treating pathology and working with modalities designed to nourish vital energy or promote system integrity.

Dr. J. William LaValley, CAM Practitioner, indicated that a network exists of expert CAM providers who could assist the OAM in identifying practices for assessment. The OAM should consider collaborating with the Canadian Cancer Society and National Cancer Institute on a Canadian breast cancer research effort involving the conventional and unconventional cancer therapy and research communities, patients, and other stakeholders. Because patients with chronic degenerative diseases nearly always are receiving multiple interventions simultaneously, the OAM should begin analyzing groups of prospective randomized trials and N=1 trials. A definition of wellness and wellness measures are needed.

A group at the April 1995 OAM methodologies conference is preparing a paper on outcomes measurement that addresses factors such as quality of life and general wellbeing, Dr. Jonas noted. Another group examined nonspecific and placebo

effects; methodological issues and research needs will be considered in more detail at a followup meeting.

Dr. Hope Kellman, Research Director, Health Technologies stated that a congressional review of the FDA was conducted in August 1996 and that a reform process is underway. An AMPAC member could serve as FDA liaison for the CAM community.

Mr. Maury Silverman, (Silver Spring, MD), stated that the OAM should use outcome data to attract interest in, and funding for, the type of studies sought after by the mainstream scientific community and the FDA. By prohibiting the exclusion of persons with pre-existing conditions, the recent Kennedy-Kassenbaum insurance bill began creating incentives, through the law, for delivery systems and the medical profession to identify more therapeutically sound and cost effective modalities. The OAM's strategic planning should take into account this important development. The passage of the Access to Medical Treatment Act is anticipated in the new Congress.

Barbara Mayerman, Holistic Health Practitioner, emphasized the need to remember that humans are whole beings. Acknowledging this wholeness was one of the reasons that the OAM was established. CAM research that reflects a disease orientation rather than a balanced approach incorporating wholeness concepts as well as good science could lead to situations in which wholistic practitioners are prohibited from treating clients for particular conditions.

#### **IX. ADJOURNMENT**

The seventh meeting of the AMPAC was adjourned at 1:00 p.m.\* on September 17, 1996.

#### **X. APPENDICES**

- A. AMPAC Meeting Agenda
- B. AMPAC Roster

NOTE: Open-session materials are available from the Executive Secretary or the Committee Management Officer.

#### **XI. CERTIFICATION**

We hereby certify that the foregoing minutes and supplements are accurate and complete to the best of our knowledge.

\_\_\_\_\_  
James S. Gordon, M.D .  
Chair  
Alternative Medicine Program  
Advisory Council  
and  
Clinical Professor  
Departments of Psychiatry and  
Family Medicine  
Georgetown University  
and  
Director  
Center for Mind-Body Medicine

\_\_\_\_\_  
Date

\_\_\_\_\_  
Geoffrey P. Cheung, Ph.D.  
Executive Secretary  
Alternative Medicine Program  
Advisory Council  
Office of Alternative Medicine  
National Institutes of Health

\_\_\_\_\_  
Date

Corrections or notations to these minutes will be  
incorporated into the minutes of the next AMPAC meeting.

**APPENDIX A**

**AGENDA**  
**SEVENTH MEETING**  
**OF THE**  
**ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL**  
**SEPTEMBER 16-17, 1996**

[Insert from briefing book.]

**APPENDIX A**

**AGENDA (CONTINUED)**

[Insert from briefing book.]

**APPENDIX B**

**ROSTER**

**ALTERNATIVE MEDICINE PROGRAM ADVISORY COUNCIL**

**SEPTEMBER 1996**

[Insert from briefing book.]



**APPENDIX B**

**ROSTER (CONTINUED)**

[Insert from briefing book.]